

## **REMARKS/ARGUMENTS**

### **Status of the Claims.**

Claims 1, 2, 4-12, and 14-20 are pending with entry of this amendment. Claims 1 and 11 are amended herein. Support for these amendments can be found in the specification at least at page 5, lines 2-34. Accordingly, these amendments introduce no new matter.

### **35 U.S.C. § 112, First Paragraph.**

Claims 1, 2, 4-12, and 14-20 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Office Action, page 2. Specifically, the Examiner contended that Applicants' specification contained "insufficient descriptive support for the generic element 'A-type cyclitol-containing carbohydrate substance comprising a  $Zn^{2+}$  ion.'" *Id.* at page 3. Applicants have amended claims 1 and 11 to replace this term with "A-type IPG substance," as the Examiner suggested. Withdrawal of the rejection is therefore respectfully requested.

### **35 U.S.C § 102.**

Claims 1, 2, 5-7, 8, and 9 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Huang *et al.*, Endocrinology (1993) 132:652-57. Office Action, page 4. This rejection is respectfully traversed.

Independent claim 1 recites:

A monoclonal antibody that specifically binds to an isolated A-type substance obtainable from human liver or placenta, wherein the substance is an A-type inositolphosphoglycan (IPG) substance that has a biological activity of regulating lipogenic activity and inhibiting cAMP dependent protein kinase.

Each of the remaining rejected claims depends from claim 1 or otherwise recites the monoclonal antibody of claim 1.

In explaining the rejection, the Examiner stated:

Huang *et al.* disclose the invention substantially as claimed. Specifically, Huang *et al.* teach an inositol phosphoglycan antibody which blocks the effects of a pH 1.3 mediator isolated from liver. Huang *et al.* disclose that the pH 1.3 mediator contains myo-inositol and inhibits cAMP-dependent protein kinase. Huang *et al.* also disclose an assay method, where the antibody is pre-incubated with

inositol phosphoglycan mediators and determining [sic] whether the antibody binds to the sample by observing that the mediators activities are completely inhibited.

The only antibody disclosed in Huang is a polyclonal antiserum "raised against variable surface glycoproteins (VSG) from Trypanosome brucei." Huang, page 654, col. 1. The preparation of this antibody is described in Romero et al., Proc. Natl. Acad. Sci. U.S.A. (1990) 87:1476-80 (previously submitted to the Office with an Information Disclosure Statement). Romero describes this antiserum in the second full paragraph of the paper and in the "Preparation of Antibodies" section, both on page 1476. The Romero article states that " $\alpha$ -Galactosidase-treated sVSG . . . was used to immunize New Zealand rabbits by using conventional procedures." Romero, page 1476, col. 2. Romero also discloses binding assays aimed at characterizing the binding specificity of the antiserum, which showed that the antibodies bound to an unidentified glycopospholipid and its head group as well as to certain forms of VSG, but not to a number of inositol-containing compounds. Romero, page 1477, para. bridging first and second cols. Accordingly, the antibody disclosed in Huang is a polyclonal antibody specific for the GPI anchor of VSG that serendipitously cross-reacts with IPGs.

By contrast, claim 1 recites a monoclonal antibody that binds to an A-type inositolphosphoglycan (IPG) substance. The differences between a monoclonal antibody and a polyclonal antiserum are significant and well-known. Generally, monoclonal antibodies are preferred, especially for use in immunoassays, because they are mono-specific, *i.e.*, they bind to a single epitope. A polyclonal antiserum contains a mixture of different antibodies, with different specificities and greater risk of undesirable cross-reactivity. Because claim 1 recites a monoclonal antibody, whereas Huang discloses a polyclonal antiserum, Huang does not anticipate claim 1. Because claims 2, 5-7, 8, and 9 incorporate the monoclonal antibody of claim 1, by virtue of their dependence from claim 1 or otherwise, these claims clearly distinguish the Huang antiserum. Withdrawal of the § 102 rejection is therefore respectfully requested.

**35 U.S.C § 103.**

Claim 4 was rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Huang *et al.* Office Action, page 5. This rejection is respectfully traversed.

Claim 4 recites: "A pharmaceutical composition comprising the monoclonal antibody of claim 1 in combination with a pharmaceutically acceptable carrier."

The Examiner stated that "it would have be obvious to one of ordinary skill at the time the invention was made to modify the antibody into a pharmaceutical composition because the disclosed antibodies have pharmacological activity." Office Action, page 5. However, as explained above, the polyclonal antiserum of Huang does not teach the monoclonal antibody of claim 1, which is incorporated into pharmaceutical composition of claim 4. Accordingly, Huang does not teach or suggest the pharmaceutical composition of claim 4. Withdrawal of the § 103 rejection is therefore respectfully requested.

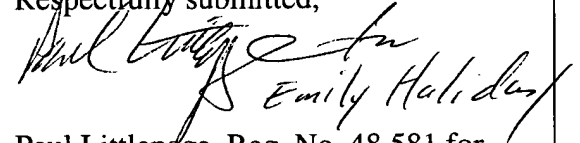
**Conclusion**

In view of the foregoing, Applicants believe that all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3509.

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Respectfully submitted,



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